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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,712	10/27/2003	Hideki Taniguchi	25682	2281
20529	7590	10/16/2006		
NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			EXAMINER POPA, ILEANA	
			ART UNIT	PAPER NUMBER
			1633	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/693,712	Applicant(s) TANIGUCHI ET AL.	
	Examiner Ileana Popa	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 14-17, 22-24, 32-37, 49, 50, 53-55 and 57-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 18-21, 25-31, 38-48, 51, 52 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the invention of Group I, drawn to a method of separating a pancreas stem cell from the pancreas of a mammal in the reply filed on 07/21/2006 is acknowledged.

Claims 6, 11, 15, 17, 20-24, 27, 32, 34, and 36 have been amended. Claims 38-74 are new. No new matter was introduced by these amendments or by the new claims.

Claims 14-17, 22-24, 32-37, 49, 50, 53-55, and 57-74 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07/21/2006.

Claims 1-13, 18-21, 25-31, 38-48, 51, 52, and 56 are under examination.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 04/24/2002. It is noted, that applicant has filed a certified copy of the PCT/JP02/04084 application as required by 35 U.S.C. 119(b). However, an English translation has not been provided. Additionally, acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 04/24/2001. It is noted, however, that applicant has not filed a certified copy of the

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2001/126315 application as required by 35 U.S.C. 119(b). Accordingly, the priority date for the instant application is considered to be 10/27/2003.

Should Applicants provide a certified translation of their foreign priority document to overcome the prior art rejection, Applicants should indicate whether the priority application is identical to the instant application, or if the priority application contains additional disclosure. If there is additional disclosure, a brief summary should be provided. Applicants should also indicate where support for each of the claim limitations (for the independent claims) can be found in the translated priority document by page and line number. If support is not found *in ipsius verbis*, clarification on the record may be helpful to the examination process.

Double Patenting

3. Applicant is advised that should claims 1-5, 40, and 43 be found allowable, claims 7-10, 25-29, 41, 42, and 45 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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5. Claims 11-13 and 40-48 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The instant claims are drawn to a pancreatic stem cell that can be separated from the pancreas of a mammal" and therefore, as written, they do not sufficiently distinguish over cells that exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. The fact that the claimed pancreatic stem cells can be separated from the pancreas of a mammal does not necessarily mean that it is separated. Therefore, claims 11-13 and 40-48 encompass a naturally occurring cell. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified" as taught by page [insert page number] of specification. See MPEP 2105.

Claim Rejections - 35 USC § 112, 2nd paragraph

6 The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

7. Claims 13 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "Flk-1" in claim 11, which is dependent on claim 1. Similarly, claim 47 recites the limitation "Flk-1" in claim 41, which is dependent on claim 7. There is insufficient antecedent basis for this limitation in claims 1 and 7.

8. Claims 28-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what Applicant means by antibody having specific affinity for a gene encoding the marker protein. While the art teaches that antibodies have specific affinity for the cognate protein antigens, the art does not teach that the same antibodies react with a gene encoding the cognate protein antigens. Therefore, the metes and bounds of the claims cannot be determined and the claims are indefinite.

9. Claims 1-10, 25-31, 38, 39, and 56 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: steps disclosing how to use the substances having affinities for the markers to separate or identify a pancreatic stem cell (claims 1-10, 38, 39, and 56), how to select cells from the pancreas (claims 25-27), or how to fractionate the population of cells (claims 28-31).

10. Claims 28-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. It is not clear what the Applicant means by a method of screening comprising "containing a population of cells with an antibody". Since cells cannot be contained with an antibody, the metes and bounds of the claims cannot be determined and the claims are indefinite. Amending the claims to recite "contacting a population of cells with an antibody" would overcome this rejection.

Claim Rejections - 35 USC § 112 – written description

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶ 1 "Written Description Requirement" makes it clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosures of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, functional characteristics coupled

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with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

Claims 1, 2, 4, and 5 encompass a variety of chemical and biological substances having specific affinity for the claimed marker protein receptors or the genes encoding them, such as antibodies, ligands, agonists, or oligonucleotides having the ability to hybridize with the genes encoding the marker protein receptors.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail such that the Artisan can reasonably conclude the inventors had possession of the claimed invention. Such possession may be demonstrated by describing the claimed invention with all its limitations using such descriptive means as words, structures, figures, diagrams, and/or formulae that fully set forth the claimed invention. Possession may be shown by an actual reduction to practice, showing that the invention was "ready for patenting", or by describing distinguishing identifying characteristics sufficient to show that the Applicants were in possession of the claimed invention (January 5, 2001, Fed. Reg., Vol. 66, No. 4, pp.1099-11).

In analyzing whether the written description requirement is met for the genus claims, it is determined whether representative numbers of species have been described by their complete structure and functional characteristics. The specification only discloses the use of antibodies to select pancreatic stem cells. Therefore,

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Applicants' invention is obtaining pancreatic stem cells, by using one specific type of agent, i.e., antibodies that specifically bind to the claimed cell surface markers. Besides antibodies and nucleic acids capable of hybridizing with the gene encoding the marker proteins, the specification does not provide any disclosure as to what would have been other substances and their mode of use for separating/identifying or obtaining pancreatic stem cells. Additionally, the specification does not describe a representative number of species (i.e., substances having specific affinity for a marker protein or a gene encoding them) by their relevant identifying characteristics, specific features and functional attributes that would distinguish different members of the claimed genus. In conclusion, the limited information is not sufficient to reasonably convey to one of ordinary skills in the art that the Applicants were in possession of the instant claimed invention, at the time the application was filed. Thus, it is concluded that the written description requirement is not satisfied for the claimed genus.

Claim Rejections - 35 USC § 112 - enablement

13. Claims 1-3, 7, 8, 11, 25-27, 38, 40-42, and 56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of separating a pancreatic stem cell by using antibodies having specific affinity for c-Met, c-kit, CD45, TER119 proteins and, optionally, by further using antibodies having affinity for Flk-1, does not reasonably provide enablement for a method of separating/identifying a pancreatic stem cells by using two or more kinds of substances having specific affinity for a marker protein selected from the group consisting of c-Met,

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use of stem cell separation by using the claimed markers. With respect to the limitation of a cloned pluripotent pancreatic stem cell (claims 19, 51, and 52), since the stem cell potential is assessed by the ability to form colonies, the isolated pancreatic stem cells are cloned pluripotent stem cells. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

17. No claim is allowed. No claim is free of prior art.

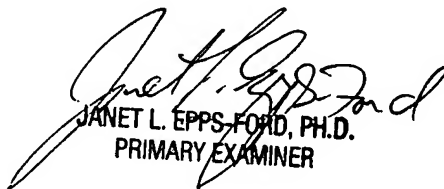
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ileana Popa whose telephone number is 571-272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ileana Popa, PhD


JANET L. EPPS-FORD, PH.D.
PRIMARY EXAMINER